

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 9, 16, 25-30 and 32-38 are pending in the application, with claims 9 and 36-38 being the independent claims. New claims 36-38 have been added. New claims 36-38 are independent claims which correspond to the composition of claim 25, where each individual element ((a), (b) and (c)) within the Markush group of part (ii) of claim 25 is recited separately in claims 36, 37 and 38, respectively. As such new claims 36-38 do not constitute new matter and require no further examination. Support for the new claims can be found, *inter alia*, at page 16, lines 6-11; page 16, line 27 through page 17 line 2; and page 22, lines 3-8.

Based on the above Amendment and the following Remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Allowed Claims***

Applicants thank the Examiner for allowing claims 9, 16 and 31.

***Rejections under 35 U.S.C. § 112***

Claims 25-30 and 32-35 were rejected under 35 U.C.S. § 112, first paragraph for allegedly failing to comply with the written description requirement. (Office Action, Page 2, ¶6) Applicants respectfully disagree and traverse the rejection.

The test for the written description requirement is whether one skilled in the art can reasonably conclude that the inventor has possession of the claimed invention in the

specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); See M.P.E.P. § 2163.02. Generally, the written description requirement is met if the patent specification describes the invention "in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.'" *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997). Furthermore, the specification need not disclose the limitations of the claim in exactly the same words as recited in the claim, but only so clearly that persons of ordinary skill in the art would recognize from the disclosure that applicant's invention included those limitations. See *Eisentein v. Frank*, 52 F.3d 1035, 1039 (Fed. Cir. 1995); *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989); *In re Smythe*, 480 F.2d 1376 (CCPA 1973). "The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,'" *Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 1000 (Fed. Cir. 2000); see also M.P.E.P. § 2163.02 ("The subject matter of the claim need not be described literally (*i.e.*, using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement.").

The Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. See *In re Wertheim*, 541 F.2d 257, 265 (CCPA 1976); *Ex parte Sorenson*, 3 USPQ2d 1462, 1463 (Bd. Pat. App. & Inter. 1987). Arguing nothing more than a lack of literal support is not enough to support a rejection under 35 U.S.C. § 112, first paragraph. See *In re Wertheim*, 541 F.2d at 265.

The Examiner has alleged. "[r]egarding the lipid of part ii)(b) [of claim 25], the cited passages of the specification disclose the use of lipids in pharmaceutical compositions, whilst the claimed invention is not drawn to a pharmaceutical composition and encompasses compositions other than a pharmaceutical composition." (Office Action, page 2, ¶6.) The sole basis of the Examiner's allegation for lack of written description is that there is no literal support for the use of the lipid as recited. However, as noted above, arguing nothing more than a lack of literal support is not enough to support a rejection under 35 U.S.C. § 112, first paragraph. *See In re Wertheim*, 541 F.2d at 265.

Applicants assert that the issue is not whether specific embodiments are *explicitly* described, but rather whether one of ordinary skill in the art, in view of the specification, could derive the claimed composition. Indeed, the Federal Circuit in *Unocal* has noted that "the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure." *Unocal*, 208 F.3d at 1001. In the present case, one of ordinary skill in the art can readily derive the claimed composition. The specification clearly teaches Applicants' claimed peptide and clearly teaches a composition comprising Applicants' peptide. This is supported by the fact that claim 9, which is directed to a composition comprising a peptide of less than about 15 amino acids in length where the peptide comprises the sequence SMPPPGTRV, is allowed, and therefore satisfies the requirements under 35 U.S.C. § 112.

Claim 25 ii)(b) simply corresponds to an embodiment of the claimed invention, where the peptide is linked to a lipid. Furthermore, the specification teaches compositions comprising a peptide where the peptide can be linked to a lipid. (*See*

Specification, page 16, line 27 through page 17, line 2.) Thus, one of ordinary skill in the art, in view of the specification, could readily derive a composition comprising the claimed peptide, where the peptide is linked to a lipid.

The Examiner further alleges that "[t]here is no support in the cited passages of the specification for the peptide of ii)(c) [of claim 25]. Regarding the specification, page 22, said passage is drawn to vaccines and the claimed invention is not a vaccine. Furthermore, said passage refers to 'different antigenic determinants of the virus or tumor cells.'"

Applicants again assert that any composition of the taught peptide would be easily and readily understood by one of ordinary skill in the art. Furthermore, Applicants note that the specification at page 22, lines 3-8, clearly teaches a peptide linked to a different CTL-inducing peptide (*i.e.*, heteropolymer). The Examiner is again making an allegation based on a lack of literal support, which does not meet the burden of proof under 35 U.S.C. § 112, first paragraph for lack of written description.

Applicants emphasize that claim 25 part (ii) is merely rephrased to consolidate Applicants' claims, and there is no requirement that Applicants' choice of language be present in the specification verbatim. As described above, the specification clearly teaches the type of peptide moieties recited in claim 25, parts ii)(b) and ii)(c).

The Examiner also alleges "[t]here is also no support for the limitation of section ii) line 1." (Office Action, page 3, ¶ 6.) Applicants again emphasize that the "written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed,'" *Union Oil of Cal. v. Atlantic*

*Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000). The term "moiety" means "[a] portion: a part." Webster's II New Riverside Dictionary, Houghton Mifflin Company (1996). Therefore, based on a standard dictionary definition of the term "moiety," a person of ordinary skill in the art, in view of the specification, would readily understand the meaning of "[a] composition comprising . . . one or more moieties . . . ." as recited in claim 25. As such, Applicants' claimed invention is adequately described in accordance with the requirements of 35 U.S.C. § 112, first paragraph.

Finally, while not acquiescing to the Examiner's rejections, Applicants have added new claims 36-38 in order to present the subject matter of claim 25 in independent claims which do not recite the term "moiety." Applicants note that new claims 36-38 correspond to the composition of claim 25, where each individual element ((a), (b) and (c)) within the Markush group of part (ii) of claim 25 is recited separately in claims 36, 37 and 38, respectively.

In summary, compositions of any of the peptide moieties recited in claim 25 would be clearly recognized by persons of ordinary skill in the art as part of Applicants' invention as claimed. The Examiner has not provided any evidence or reason why this is not the case; the Examiner is merely arguing lack of literal support, which does not meet his burden of proof for the rejection.

Finally, the Examiner alleges that "[t]here is no support in the specification as originally filed for the composition of claims 32-35. . . said passage discloses an in vitro assay to determine whether a peptide can invoke a CTL where said assay uses a APC or dendritic cell. It does not disclose the claimed composition containing a APC or dendritic cell." (Office Action, page 3, ¶ 6.) As the Examiner has noted, the

specification *does* disclose an APC and a dendritic cell at page 40, lines 9-14. (*Id.*) Applicants point out that the specification also teaches compositions comprising an immunogenic peptide and APC (which includes dendritic cell) at page 26, lines 17-20.

The Examiner again relies on an argument that the specified claim does not have literal support. Furthermore, the Examiner's allegations focus on the use of an APC or a dendritic cell, when *no specific use of the composition is being claimed*. In view of the specification, one of ordinary skill in the art would readily understand what the terms "antigen presenting cell (APC)" and "dendritic cell" in claims 32-35 mean. The specification need not disclose "APC" or "dendritic cell" in exactly the same words as claimed, but only so clearly that persons of ordinary skill in the art would recognize from the disclosure that applicant's invention included those limitations. *See Eiseltein v. Frank*, 52 F.3d at 1039. As Applicants' specification clearly teaches these terms, the written description requirements under 35 U.S.C. § 112, first paragraph, have been adequately satisfied. Accordingly, Applicants respectfully request that the rejection of claims 25-30 and 32-35 under 35 U.S.C. § 112, first paragraph, be withdrawn.

***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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